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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GAMBEL, PHILLIP	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 03/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/874,141	DARRELL ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3,5 and 16-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3,5 and 16-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 12/16/03, has been entered.
Claims 1, 4 and 6-15 have been canceled.

Claims 2, 3, and 5 have been amended.
Applicant is invited to clarify whether the recitation of "4" on line 1 of claim 5 is crossed out or not.

Claims 16-39 have been added.

Claims 2, 3, 5 and 16-39 are pending.

Applicant's election with traverse, filed 4/3/03, of multiple sclerosis (Group II-C) as the disease species has been acknowledged.

Claims 2, 3, 5 and 16-39 as they read on treating multiple sclerosis with anti-gp39 antibodies are under consideration as the elected invention.

For examination purposes, claim 3 is being included only to the extent that IL-2 secretion would be a by-product of the inflammatory response of multiple sclerosis or a property of anti-gp39 (anti-CD40 ligand) antibodies in the claimed methods. IL-2 secretion itself does not cause multiple sclerosis.

2. Again, the filing date of the instant claims is deemed to be the filing date of the provisional application 60/209,584, filed 6/6/00.

Applicant's reference to the relationship of USSN 08/554,840 with the instant application is acknowledged. However as pointed out previously, applicant cannot claim priority USSN 08/554,950, filed 11/7/95, now U.S. Patent No. 6,001,358, which issued 12/14/99 because there was no copendency between the instant USSN 09/874,141 and USSN 08/554,950.

Therefore, applicant disclosure of a "relationship" between the instant application and USSN 08/554,840 does not provide for priority back to USSN 08/554,840.

Also, see United States Patent and Trademark Office OG Notices: 1268 OG 89 (18 March 2003).

3. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 2, 3, 5 and 16-39 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. The specification as originally filed does not provide support for the invention as now claimed:

"Substantially non-agonistic of T cell co-stimulation responses / IL-2 secretion by T cells" and
"at least one cytokine by T cells".

Applicant's amendment, filed 12/16/03, asserts that the support for the newly amended and added claims are supported by the specification (e.g., see pages 31-37 and Examples).

The specification as filed does not provide a sufficient written description nor set forth the metes and bounds of this phrase. The specification does not provide blazemarks nor direction for the instant methods encompassing the above-mentioned "limitations", particularly with respect to the recitation of "substantially" and "at least one" as currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office action

Alternatively, applicant is invited to provide sufficient written support for the "limitations" indicated above. See MPEP 714.02 and 2163.06

5. Claims 2, 3, 5, 16-31 and 34-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for determining the effect of an anti-gp39 antibody on the induction of production of "IL-2, IL-4 and gamma interferon" as the measure of T cell costimulation responses; does not reasonably provide enablement for "at least one cytokine by T cells" or any "T cell costimulation response". The specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to make and use the invention commensurate in scope with these claims.

While the specification provides guidance and direction to determining the production of "IL-2, IL-4 and gamma interferon" (e.g. see page 35, paragraph 1 of the instant specification) in determining the properties of non-agonistic anti-gp39 antibodies, there is insufficient guidance and direction as to the scope of possible cytokine produced by T cells that can or should be measured in the context of the instant methods. T cells comprise a variety of cells which produce a variety of cytokines. There is insufficient guidance and direction as to which cytokine among the number of possible cytokines should be measured in determining the inhibitory properties of anti-gp39 antibodies. There is insufficient guidance and direction as to which cytokines other than "IL-2, IL-4 and gamma interferon" would be predictive of the desired non-agonistic properties of anti-gp39 and, in turn, would be predictive of the claimed therapeutic endpoints. In addition, applicant has not provided sufficient direction as how to measure cytokines other than IL-2, IL-4 and gamma interferon.

As pointed out on page 35, lines 29-31, the study of T cell interactions can be complex, due to the presence of numerous accessory cell types capable of mediating redundant or interdependent costimulatory effects.

The scope of the claims must bear a reasonable correlation with the scope of enablement. See In re Fisher, 166 USPQ 18 24 (CCPA 1970).

Applicant is invited to limit the claims to the recitation of "IL-2, IL-4 and gamma interferon".

8. Claims 2, 3, 5 and 24-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention

It is apparent that the 24-31 antibody is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the cell line / hybridoma which produces this antibody. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the original deposit is made after the effective filing date of an application for patent, the applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified. See MPEP 1.804(b).

It is noted that the sequence of an entire immunoglobulin satisfies the biological deposit of said immunoglobulin. Note that satisfaction for the biological deposit of the specific 24-31 antibody requires the disclosure and recitation of its entire amino acid sequence and not based upon partial sequences.

9. Applicant's amended claims have obviate the previous rejections under 35 U.S.C. § 112, second paragraph.

10. Claims 2, 3, 5 and 16-39 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 2, 3, 5 and 16-39 are indefinite in that they do not set forth clearly the method steps to carry out the claimed "screening" for anti-gp39 antibodies inhibit gp39-CD40 interactions, for determining the effect of an anti-gp39 antibodies on the induction or production of at least cytokine by T cells, including the induction or production of gamma interferon and Il-2 by T cells. Therefore, the instant claims are incomplete as they omit essential steps. The instant claims do not set forth clear, distinct and positive process steps with the claimed screening aspect of the claimed methods.

B) Claims 2, 3, 5 and 24-30 are indefinite in the recitation of "24-31" because its characteristics are not known. The use of "24-31" monoclonal antibody (or the variable region amino acid sequences) as the sole means of identifying the claimed antibody renders the claim indefinite because "24-31" is merely a laboratory designation which does not clearly define the claimed product, since different laboratories may use the same laboratory designation s to define completely distinct hybridomas or cell lines.

As pointed out above, the recitation of partial sequences such as variable region amino acid sequences does not defined the complete amino acid sequence of the claimed 24-31 antibody

Applicant is invited to satisfy the deposit requirements under 35 USC 112, first paragraph, and recite the appropriate deposit accession number or to amend the claims to recite the claimed 24-31 antibody in terms of reciting the ant-gp39 antibody specificity in terms of variable region amino acid sequences rather than the 24-31 specificity.

C) Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 2, 3, 5,16-30 and 36-39 are rejected under 35 U.S.C. § 102(a)(e) as being anticipated by Black et al. (U.S. Patent No. 6,001,358) (see entire document).

Black et al. teach methods of treating disease condition wherein gp39 inhibition is therapeutically beneficial (columns 13-14 and 31-34), including multiple sclerosis with column 14, line 40 and column 32, line 67) with antibodies that bind gp39 (CD40 ligand), which block signals delivered via CD40 (See Examples 2, 3 columns 22-23; Examples 11-17 on columns 28-38 (see entire document). In addition, Black et al. teach chimeric, humanized and primatized antibodies, including the use of different heavy chain constant regions (IgG1, IgG3, IgG4), with conservative amino acid substitutions such as Kabat positions 229 and 236 as well as the 24-31 antibody specificity and its variable region amino acid sequences encompassed by the claimed methods (see entire document, including Background of the Invention, including columns 6-7; Summary of the Invention, Detailed Description of the Invention, including columns 13 –22; Claims). Further, it is noted that Black et al. teach that it was known that $gp39^+$ T cells produce Il-2, IL-4 and gamma interferon (see column 4, paragraph 1). In addition, Black et al. teach modes of administrations and dosages of antagonistic anti-gp39 antibodies encompassed by the claimed methods (see columns 33-38).

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced methods to treat multiple sclerosis with anti-gp39 (anti-CD40 ligand antibodies). It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure

For examination purposes, this prior art rejection includes those claims that do not specifically recite determining the effect of anti-gp39 antibodies on the production of IL-2 and gamma interferon or T cell proliferation per se. Black et al. clearly teach screening and measuring inhibitory anti-gp39 antibodies, including measuring functional inactivation of gp39 in vitro and in vivo (see Detailed Description and Examples).

Applicant's arguments, filed 12/16/03, have been fully considered but are not found convincing for the reasons of record and set forth herein.

Applicant argues that Black et al. does not describe nor suggest assaying anti-gp39 antibodies to determine if they are non-antagonistic of T cell costimulation responses such as the induction of cytokine production or proliferation by T cells.

Applicant's assertions that the ordinary artisan could not have predicted that it was possible to select non-agonistic anti-gp39 antibodies of T cell costimulation responses runs in direct contrast to the clear teachings of the in vitro and in vivo inhibitory anti-gp39 antibodies and their use to treat various conditions, including multiple sclerosis, as well as the known ability of $gp39^+$ T cells to produce Il-2, IL-4 and gamma interferon, in the prior art. Although the prior art clearly defines the use of inhibitory anti-gp39 antibodies rather than the instant terminology of "non-agonistic" anti-gp39 antibodies, it is clear that the prior art employs the same anti-gp39 antibodies to achieve the same therapeutic endpoints with the clear knowledge of the role of $gp39^+$ T cells in various interactions and in producing various cytokines to achieve such interactions.

Applicant arguments are not found persuasive.

14. Claims 2, 3, 5, 16, 17, 19-28, 30 and 36-37 are rejected under 35 U.S.C. § 102(e) as being anticipated by Noelle et al. (U.S. Patent No. 6,328,964) (see entire document).

Noelle et al. teach methods of treating T cell mediated disorders such as multiple sclerosis with anti-gp39 (anti-CD40 ligand) antibodies (see entire document; including Summary of the Invention on column 2; T Cell Mediated Autoimmune Diseases on column 3 and Claims 1-6). Noelle et al. teach the known use of chimeric and humanized antibodies as well as methods of producing recombinant anti-gp39 antibodies, as well as the specific 24-31 anti-gp39 antibody specificity (see Antibodies, columns 3-6). Although the reference is silent about the exact variable domain amino acid sequences of the 24-31 antibody as well as its constant domains and conservative substitutions, these amino acid sequences and conservative substitutions were inherent properties of the specific 24-31 antibody and the manipulation to humanize said antibody (see column 5-6). Noelle et al. teach methods of administering said antibodies (see column 6, paragraph 2 - column 8).

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced methods to treat multiple sclerosis with anti-gp39 (anti-CD40 ligand antibodies). It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure

Applicant's arguments, filed 12/16/03, have been fully considered but are not found convincing for the reasons of record and set forth herein.

Applicant argues that Noelle et al. does not describe nor suggest assaying anti-gp39 antibodies to determine if they are non-antagonistic of T cell costimulation responses such as the induction of cytokine production or proliferation by T cells.

Applicant's assertions that the ordinary artisan could not have predicted that it was possible to select non-agonistic anti-gp39 antibodies of T cell costimulation responses runs in direct contrast to the clear teachings of the in vitro and in vivo inhibitory anti-gp39 antibodies and their use to treat various conditions, including T cell mediated autoimmune diseases, including multiple sclerosis. Although the prior art clearly defines the use of inhibitory anti-gp39 antibodies rather than the instant terminology of "non-agonistic" anti-gp39 antibodies, it is clear that the prior art employs the same anti-gp39 antibodies to achieve the same therapeutic endpoints with the clear knowledge of the role of $gp39^+$ T cells in various interactions and in producing various cytokines to achieve such interactions.

Applicant arguments are not found persuasive.

15. Claims 2, 3, 5 and 16-39 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Black et al. (U.S. Patent No. 6,001,358) (see entire document) in view of art known methods to screen for inhibitors of cytokines, as taught by Schrader et al. (U.S. Patent No. 5,627,052) and Burkly et al. (US2002/0028202 A1).

Black et al. teach methods of treating disease condition wherein gp39 inhibition is therapeutically beneficial (columns 13-14 and 31-34), including multiple sclerosis with column 14, line 40 and column 32, line 67) with antibodies that bind gp39 (CD40 ligand), which block signals delivered via CD40 (See Examples 2, 3 columns 22-23; Examples 11-17 on columns 28-38 (see entire document). In addition, Black et al. teach chimeric, humanized and primatized antibodies, including the use of different heavy chain constant regions (IgG1, IgG3, IgG4), with conservative amino acid substitutions such as Kabat positions 229 and 236 as well as the 24-31 antibody specificity and its variable region amino acid sequences encompassed by the claimed methods (see entire document, including Background of the Invention, including columns 6-7; Summary of the Invention, Detailed Description of the Invention, including columns 13 –22; Claims). Further, it is noted that Black et al. teach that it was known that $gp39^+$ T cells produce Il-2, IL-4 and gamma interferon (see column 4, paragraph 1). In addition, Black et al. teach modes of administrations and dosages of antagonistic anti-gp39 antibodies encompassed by the claimed methods (see columns 33-38).

Black et al. differs from the claimed methods by not disclosing the art known use of screening for inhibitors of cytokine activity such as IL-2 and gamma interferon in selecting for antagonistic anti-gp39 specific antibodies per se.

Again, it is noted that Black et al. teach that it was known that $gp39^+$ T cells produce Il-2, IL-4 and gamma interferon (see column 4, paragraph 1).

Schrader et al. teach methods of producing antibodies of a desired function to a variety of antigens, including IL-2 and gamma interferon, including the selection of antibodies that neutralizes a growth factor or other biologically active molecule (e.g. see columns 8-9, overlapping paragraph) and exemplifies the detection of antibodies that neutralize IL-2 (see Example 1 on columns 21-22) (see entire document, including Summary of the Invention and Detailed Description of the Invention).

Burkly et al. teach known methods of assaying or screening the ability of antagonists such as antibodies to block a response to a particular cytokine (e.g. IL-2) (see Gc chain Blocking Agents and Production of GC Blocking Antibodies on pages 7-8 and Testing Compounds of the Invention for Biological Utility on page 13). Burkly et al. notes it will be recognized by one skilled in the art, that these screens can be arranged to discover antibodies whose activities are conspicuous in one or more of these assays (see paragraph 095 on page 8) and that one of skill in art may easily determined using well known methods whether a particular blocking agent displays biological utility (see Testing Compounds of the Invention for Biological Utility on page 13).

Therefore, it would have obvious to a person of ordinary skill in the art at the time the invention was made to apply the teachings of Schrader et al. and Burkly et al. to those of Black et al. to obtain screen for antagonistic antigp39 antibodies with the ability to inhibit cytokines produced by activated T cells, including the inhibition of IL-2 and gamma interferon, known to be a product of such cells and to be a target of antagonistic anti-gp39 antibodies. According to Black et al., a person of ordinary skill in the art would have been motivated to produce this resultant ability of anti-gp39 to inhibit cytokine production by activated T cells in order to test and select for those anti-gp39 antibodies that had the desired properties of inhibiting gp39:CD40 interactions and the resultant ability of such antibodies to inhibit T cell mediated activation of immune responses in the treatment of various conditions and disorders, including multiple sclerosis. Therefore, a person of ordinary skill in the art would have a reasonable expectation of success at the time the invention was made. . Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

16. No claim allowed.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
March 29, 2004